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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,532	11/25/2003	Christoph Erbacher	QGN-008.1 US-2	5346
<div>7590      08/03/2007 Leon R. Yankwich YANKWICH &amp; ASSOCIATES 201 Broadway Cambridge, MA 02139</div>			<div>EXAMINER BURKHART, MICHAEL D</div> <div>ART UNIT      PAPER NUMBER 1633</div> <div>MAIL DATE      DELIVERY MODE 08/03/2007      PAPER</div>	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/721,532

Applicant(s)

ERBACHER ET AL.

Examiner

Michael D. Burkhardt

Art Unit

1633

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 02 July 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The Notice of Appeal was filed on 02 July 2007. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).


4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 18-46.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

  
SUMESH KAUSHAL, PH.D.  
PRIMARY EXAMINER

Continuation of 3. NOTE: Claim 18 (from which claims 19-46 depend) has been amended to recite that the claimed compounds have the ability to deliver exogenous compounds in vivo or in vitro. This limitation was not previously recited in the claims. Hence the specification and prior art would have to be searched and considered for, in particular, the in vivo use of the claimed compounds to deliver exogenous compounds. It would have to be determined if the specification, combined with any relevant prior art, satisfied the requirements of 35 USC 112 1st paragraph regarding how to use the claimed compounds in vivo commensurate in scope with the claims..

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 18-20 and 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Milieva et al (J Appl Toxicol., (1995)).

Claims 18-20, 23-25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sykora et al (Folia Microbiol., (1991)).

Claims 18-20, 23-25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by GB1277086.

The above rejections are maintained for reasons made of record in the previous Office Actions (dated 12/20/2005 and 12/28/2006) and for reasons set forth below.

#### Response to Arguments

Applicant's arguments filed 7/2/2007 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) Milieva et al does not teach that the QAS compound was used to transport any ingredients of the Krebs' solution into smooth muscle cells and there is no association between the Krebs' solution and the QAS compounds; 2) Sykora et al do not teach that the BDHD compound promotes uptake of any of the exogenous compounds found in Luria Broth, Sykora et al do not disclose the use of BDHD for use in transfection, Sykora et al do not disclose BDHD is capable of intracellular delivery of exogenous compounds; 3) Sykora et al teach contacting bacteria with only BDHD, not a composition; 4) Sykora et al teaches away from using BDHD to insert a foreign molecule into a cell; 5) the '086 document does not disclose use of the QAS compounds for use in transfection, or in a composition further comprising an exogenous compound capable of intracellular delivery.

Regarding 1), 2), and 5), as set forth in the previous Office Action, the recitation of an intended use for the claimed compounds (i.e. "for intracellular delivery") does not further limit the structure of the claimed compounds. See MPEP 2111.02 and the text from MPEP 2111.02 cited in the previous Office Action. Because the cited references teach all the structural limitations of the claimed compositions, the claims are anticipated by the references.

Further regarding 1), the experiments of Milieva et al on smooth muscle cells were conducted in Krebs' solution for reasons of record, to which the QAS compound was added. Read the legend to Fig. 1 and the Results section beginning on page 220. Further regarding 3), for reasons of record, Sykora et al teach a composition comprising BDHD with both peptides and sodium chloride, both of which are within the scope of exogenous compounds recited in claim 18. Regarding 4) "teaching away from" is not a consideration in 35 USC 102 rejections, but rather belongs in arguments directed to 35 USC 103 rejections. Further regarding 5), the '086 document teaches QAS compounds used in conjunction with a surface active agent, such as sodium lauryl sulfate. It was explained in the previous Office Action that sodium lauryl sulfate is considered a pharmaceutical compound due to its use in shampoos, toothpastes, and pharmaceutical preparations.

Claims 18-26, 28-38, and 40-44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, and 11-46 of U.S. Patent No. 6,733,777. This rejection is maintained for reasons set forth in the Office Actions dated 12/20/2005 and 12/28/2006, and for reasons set forth below.

#### Response to Arguments

Applicant's arguments filed 7/2/2007 have been fully considered but they are not persuasive. Applicants essentially assert that a restriction requirement between Group I (methods of delivery) and Group II (cationic cytofectins) in the parent application, which issued as 6,733,777, prevents the instant rejection. The fact that the restriction requirement was vacated in the parent application does not apply as a reason to maintain the instant rejection because the '777 claims were amended to the format of method claims.

A review of the '777 claims reveals claims to both compositions (claims 11 and 29-46) and methods (e.g. claims 1-8). Thus, in contrast to applicants assertions, it appears Groups I and II from above were indeed rejoined in the parent case. All of the issued claims were not amended to be in the format of method claims.

Claims 33, 45 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained for reasons set forth in the Office Action dated 12/28/2006, and for reasons set forth below.

#### Response to Arguments

Applicant's arguments filed 7/2/2007 have been fully considered but they are not persuasive. Applicants essentially assert that the scope of "lipid-like" molecule is clearly defined in the specification because "liposome", according to the present invention, denotes a structure comprised of, inter alia, lipid-like molecules.

Such is not convincing because the specification merely recites examples of lipid-like molecules (i.e. "such as 1,2-dioleoyloxiphosphatidylethanolamine") in the context of a liposome. This is not a definition of what constitutes a lipid-like molecule, but merely an example of a single species that could be considered a lipid-like molecule. Thus, it provides no help in determining the metes and bounds of the phrase "lipid-like."

With respect to claims 45 and 46, applicants arguments are directed to the amended claims. Because the amendment has not been entered, these arguments are moot.

Claim 39, 45, and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This rejection is maintained for reasons set forth in the Office Action 12/28/2006 and for reasons set forth below.

With respect to claims 39, 45 and 46, applicants arguments are directed to the amended claims. Because the amendment has not been entered, these arguments are moot.